

MEDS-ALERT USA, INC. 1451 Parkview Terrace, S. Algonquin, IL 60102 847-658-6784

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OPENING STATEMENT

- 1. GOOD AFTERNOON LADIES AND GENTLEMEN
- 2. I'M TERRY O'BRIEN, PRESIDENT AND FOUNDER OF MEDS-ALERT USA, INC..
- 3. I WANT TO THANK MARY GROSS AND OTHERS AT THE FDA FOR THE OPPORTUNITY TO SPEAK TODAY.
- 4. AS WE ALL KNOW, BAR CODES ARE BEING TARGETED AS A WAY TO REDUCE MEDICATION ERRORS AND INCREASE PRODUCTIVITY OF THE HEALTH CARE DELIVERY SYSTEM. WE HAVE BEGUN WORK WITH THE UNIVERSITY OF TENNESSEE (DR. DICK GOURLEY, DEAN, COLLEGE OF PHARMACY) TO THAT END.
- 5. THE BAD NEWS: AS MANY AS 90 THOUSAND PEOPLE DIE AND 1.3 MILLION INJURED PER YEAR FROM MIXED UP MEDICATIONS.

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- 6. THE GOOD NEWS: MEDS-ALERT'S SYSTEM WILL SAVE LIVES AND WILL SAVE MONEY. 600-800 MILLION DOLLARS MEDICAID HOUSING COSTS ONLY IF THE MEDS-ALERT BAR CODED SYSTEM WERE USED IN ILLINOIS GOVERNOR RYAN DIRECTOR OF AGING, MARGOT SCHRIEBER.
- 7. RECENT STUDY BY NATIONAL ASSOCIATION OF CHAIN DRUG STORES SAYS IN 2001 U.S. SPENT \$150 BILLION ON 4 BILLION PRESCRIPTIONS AND \$177 BILLION TO CORRECT THE MEDICATION ERRORS.
- 8. MEDS-ALERT HAS DEVELOPED AND PATENTED A SYSTEM TO BRING THE USE OF BAR CODED "MEDICINE" "CAREGIVERS" AND "SUPPLIES" INTO THE PATIENTS' HOMES OR THE PATIENTS' INSTITUTIONAL SETTING.
- 9. MEDS-ALERT GRANTED PATENTS BY U.S. PATENT OFFICE WITHIN SIX MONTHS BECAUSE IT WOULD HELP CANCER OR AIDS PATIENTS.
- 10. ALSO HAVE INTERNATIONAL PATENT RIGHTS FOR MOST OF THE INDUSTRIALIZED WORLD.
- 11. MEDS-ALERT COMMUNICATION LINKS: WIRED TELEPHONE, CABLE TV, WIRELESS.
- 12. HOW DOES MEDS-ALERT RAISE PRESCRIPTION COMPLIANCE:
 - 1. SIGNAL PATIENT IN ANY LANGUAGE
 - 2. VERIFY CORRECT MEDICATIONS
 - 3. SOUND ALARM FOR NON-COMPLIANCE
- 13. GOOD CARE COMPROMISED BY PATIENT NON-COMPLIANCE.

- 14. ILLITERATE OR THOSE WITH LOW HEALTH LITERACY HAVE TROUBLE READING PRESCRIPTION LABELS AND MEDICAL FORMS, AN ESTIMATED 90 MILLION PEOPLE. BAR CODES OFFER A SOLUTION.
- 15. NON-COMPLIANCE OFTEN LEADS TO THE EMERGENCY ROOM OR WORSE, INSTITUTIONALIZATION (NURSING HOME/HOSPITAL)
 THE AVERAGE COST FOR NURSING HOME STAY IS APPROXIMATELY \$50,000 PER YEAR.
- 16. KAISER FAMILY FOUNDATION STUDY RELEASED MAY 2, 2002 OF 4,000 WOMEN STUDIED 21% DID NOT EVEN FILL PRESCRIPTIONS.
- 17. MEDS-ALERT HAS SOLUTION FOR NO-FILLS TOO CALLED RESCRIBE.
- 18. CHRONIC DISEASES AGE ACCORDING TO KIPLINGER NEWSLETTER OF 6/14/02, PEOPLE WITH CHRONIC DISEASES ARE ONLY 20% OF THOSE INSURED BUT MAKE UP 80% OF HEALTHCARE COSTS AN ESTIMATED 125 MILLION OF 276 MILLION AMERICANS HAVE ONE CHRONIC DISEASE CHRONIC DISEASE MANAGEMENT, THE ONE SURE AREA TO REDUCE COSTS.
- 19. TIME MAGAZINE ARTICLE AUGUST, 2001, DR. VICTOR VILLAGRA, PRESIDENT OF DISEASE MANAGEMENT ASSOCIATION OF AMERICA AND EXECUTIVES OF CIGNA WHICH HAS 600,000 MEMBERS ENROLLED IN CHRONIC CARE PROGRAMS HAS SEEN A 14% COST SAVINGS FOR DIABETIC PATIENTS. HE SAID "THAT IS NO LONGER SUFFICIENT....WHAT IS, APPARENTLY, IS HAVING SOMEONE TELL YOU TO TAKE YOUR MEDICINE, OR ELSE.".

 "INSURANCE IS A PRIVILEGE NOT A RIGHT ARE MEDICARE AND MEDICAID HEADED IN THIS DIRECTION?".

- 20. MEDS-ALERT REMINDS SOMEONE TO TAKE THEIR MEDICATIONS AND RECORDS THE EVENT.
- 21. WHO ARE THE CHRONICALLY ILL: PATIENTS WHO SUFFER FROM HEART DISEASE, DIABETES ASTHMA, AIDS, CANCER AND AS YET UNCOUNTED AS CHRONICALLY ILL, THE TWO PLUS MILLION ORGAN TRANSPLANT RECIPIENTS. DOES COGNITIVE IMPAIRMENT COUNT TOO?
- 22. PEOPLE AND COST COMING TIDAL WAVE BOOMERS WILL MAKE UP 26% OF POPULATION BY 2010 AND ALONG WITH THEM COMES CHRONIC DISEASES AND COGNITIVE IMPAIRMENT.
- 23. SHORTAGES: YET ANOTHER UNRESOLVED PROBLEM

 CAREGIVERS DAUGHTERS PROVIDED MOST HOME
 HEALTHCARE MOST NOW WORK;

 NURSES ESTIMATED 60% OVER 40 YEARS OLD, NEED
 REPLACEMENTS;

 PHARMACISTS: 10,000 JOBS NO ONE TO FILL;
 LOW WAGES THE AVERAGE PAID CAREGIVER IN CHICAGO
 EARNS APPROXIMATELY \$18,000 PER YEAR, NOT ENOUGH TO
 PAY FOR AN APARTMENT AND FOOD.
- 24. THE ONLY WAY TO HANDLE THE OVERWHELMING PROBLEM IS AUTOMATION BAR CODED UNIT DOSE PACKAGING.
- 25. SENATOR KENNEDY AND OTHERS WILL INTRODUCE LEGISLATION THIS YEAR TO REDUCE HEALTHCARE COSTS. CURRENTLY HEALTHCARE IS 14% OF THE GROSS DOMESTIC PRODUCT HEADED TO 18% BY 2011.
- 26. BAR CODES MUST BE PART OF THE TECHNOLOGY SOLUTION.

27. NATIONAL BAR CODE STANDARD - HOW CLOSE - WHO IS WORKING ON IT - FDA - NEW LABELING RULES YET? HEALTH AND HUMAN SERVICES, UNIFORM CODE COUNCIL U.S. PHARMACOPEIA (NCCMERP), U.S. DRUG MANUFACTURERS SHOULD WANT A STANDARD FOR BAR CODES - MAIL ORDER FACILITIES.

- 28. THE ULTIMATE SOLUTION BAR CODED UNIT DOSE PACKAGING AUTOMATED BAR CODED UNIT DOSE STERILE TRACEABLE VERIFIABLE.
- 29. MEDS-ALERT STANDS READY WITH ITS PATENTED TECHNOLOGY TO ADDRESS UNIT DOSE PACKAGING.
- 30. OUR TEAM IS RESPONSIBLE FOR OVER 20 PATENTS INCLUDING.
 DIGITAL KEYBOARDS
 EMBEDDED CONTROLS
 KIDNEY DIALYSIS
 LASER SAWS
- 31. MEDS-ALERT HAS DEMONSTRATION UNITS COMPLETED AND WOULD WELCOME DISCUSSIONS WITH OTHER ENTITIES.
- 32. TEAM CONSISTS OF: UNIVERSITY OF TENNESSEE, PATENT LAWYERS, BARTHEL, ALDERMAN, SCHULTZ, BOEMAN.
- 33. MEDS-ALERT PATENTS ALLOW FOR MIGRATION AND EXPANSION.
- 34. CURRENT STATUS: DEMO MODELS COMPLETED.
- 35. THANK YOU.

MEDS-ALERT USA INC.

THE MEDS-ALERT INTERACTIVE PRESCRIPTION COMPLIANCE AND LIFE SAFETY SYSTEM

AND

RESCRIBE PRESCRIPTION FULLFILLMENT VERIFCATION SYSTEM

AND

PATENTS

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NEED IN PRODUCTIVIY AND QUALITY CARE

The creativity of the 21st century has been in the increase of productivity of the worker. Production facilities use robots. Businesses use computers and the net. Very little has occurred in increasing the productivity of medical delivery systems:

- -Limit the time a physician sees a patient;
- -Advanced testing and diagnostic machines;
- -Cutting the reimbursement of the physician;
- -Cutting the hospital or institutional stays of the patients*;
- -Advances in drug and other therapies to keep patients out of institutionalized care*.

*MEDS-ALERT USA INC. addresses the productivity of these activities.

We hear about acute care delivery (heart attacks, strokes, car accidents, etc.) but 75% of care is for chronic problems such as (major categories):

- -Congestive heart failure;
- -Diabetes;
- -Depression;
- -and other conditions.

The problem in delivering good care often lies in the patients failure to comply with prescribed treatments. This causes death or institutionalization (hospice, nursing home, hospital).

Patients have contradictive behaviors:

- -They do not want to face the disease (I do not feel bad);
- -Hence, they do not faithfully follow the medicine and treatment regimens;
- -They do not inform doctors or follow through because they greatly fear their loss of independence;

The key to increasing productivity in health care is to improve the self management of the patients. The MEDS-ALERT USA INC. system does this dramatically.

NEED IN THE MARKETPLACE

A sizable segment of the population that requires medication have difficulty with:

- -Not filling prescriptions
- -Forgetting, by mistake or on purpose, to take medications;
- -Taking the medications at proper times and intervals;
- -Taking the proper medication;
- -Double dosing;
- -Confusing and mixing up medications.

All of these actions are life threatening.

More importantly, freedom threatening to the patients. The most common cure for people with these problems is to institutionalize them, usually in nursing homes. Most of these people are older and in the beginning phases of senility, dementia or Alzheimer's Disease.

Informally, Walgreen's has told MEDS-ALERT USA INC. that an in-house study shows that if proper medication is maintained, an elderly patient, on average, could be kept out of a supervised care facility for an additional 2½ years.

It is estimated that 25% of nursing home patients are institutionalized in order to insure the proper administration of their medicines.

By some estimates, there is currently a shortage of 100,000 nurses 10,000 pharmacists. By 2010 one half of the nurses now working will be eligible for retirement. Technology must be utilized to increase the capacity of the system.

MEDS-ALERT USA INC. has a patented proprietary system to greatly enhance the proper administration medications for people at home.

MEDS-ALERT USA INC. holds the only patent utilizing Bar Codes for identifying prescriptions and caregiver identity in the home. The College of Pharmacy of the University of Tennessee has joined with MEDS-ALERT USA INC. to aid in the development of this system

OVERVIEW

The MEDS-ALERT USA INC. system assists people to take the proper medications in the proper dosages and the prescribed times.

The MEDS-ALERT USA INC. system uses:

- -Bar Coded medicines;
- -Bar Code readers in the home:
- -Interactive and monitored communication systems to the home; to insure the patients compliance with their medication regimen.

The MEDS-ALERT USA INC. system automatically and forcefully reminds patients to take their medicines at the prescribed times.

The MEDS-ALERT USA INC. system reacts to:

- -Failure to respond to the reminder;
- -Failure to take the medicine:
- -Selection of incorrect medicines;
- -Accidental double dosing by patients who cannot remember taking their medicine.
- -Need to reorder medicines or medical disposables

The MEDS-ALERT USA INC. system calls for help if a problem is detected.

The MEDS-ALERT USA INC. system is an interactive system placed in the home.

DESCRIPTION OF SERVICE

PRESCRIPTION

- 1. A physician prescribes a medication for a patient. There is some question as to the patient's ability, often because of old age, the onset of dementia or the beginning stages of Alzheimer's Disease, to correctly follow the prescribed regimen.
- 2. The patient's provider (Medicare, Medicaid, insurance company, HMO, etc.) directs the medication be administered through the MEDS-ALERT USA INC. system. This greatly reduces the possibility of incorrect medicine administration and/or the need to place the patient in an institution to insure a proper regimen of the medications application.
- 3. CURRENT: The prescription is sent to a pharmacy where it is Bar Coded for:
 - -Patient information;
 - -Medication, dosage and regimen;
 - -Refill information;
 - -Physician information
 - -Pharmacy information.

This information is relayed to MEDS-ALERT USA INC. and it is entered into the central processing system. Required data is transferred to the patient's MEDS-ALERT USA INC. unit:

- -Medicine
- -Regimen

FUTURE: The medications will be packaged by "Unit Dose Packaging", where every dose is in a separate Bar Coded package. This packaging is already in use by certain providers, specifically the Veterans Administration and General Nutrition. "Unit Dose Packaging" greatly reduces the chance for prescription errors.

FUTURE: "The Unit Dose Packages" are shipped in a cassette that is placed in the MEDS-ALERT USA INC. unit that controls their dispensing. The unit would handle up to 15 medications (cassettes) (more and patients should be institutionalized). The "cassette" system offers greatly improved security with greatly reduced dose and wrong medication errors.

FUTURE: The MEDS-ALERT USA INC. "RESCRIBE" system notifies the prescribing physician, general physician and healthcare provider of the prescription being filled.

DESCRIPTION OF SERVICE – (continued)

MEDS-ALERT USA INC. UNIT INSTALLATION

- 4. The patient's information is entered into the MEDS-ALERT USA INC. system:
 - -Patient information;
 - -Provider information (HMO, Medicare, insurance company, etc.);
 - -Physician information;
 - -Care-giver information (Home nurse, relative, neighbor, etc.);
 - -Emergency protocol for that patient.
- 5. A MEDS-ALERT USA INC. remote unit is programmed for the patient's needs and installed in the patient's home. The care-giver and patient are instructed in the unit's use:
 - -Why the MEDS-ALERT USA INC. unit is being used;
 - -How to use the unit to take medications;
 - -What will happen if there is a difficulty with the medication regimen;
 - -Additional services provided (panic button, motion sensor, video camera).

TAKING THE MEDICATION

- 6. The MEDS-ALERT USA INC. system notifies the patient to take their medicines at the appropriate times by one or more of the following:
 - -Sounding an alert (verbal ("Bill, it is time to take...");
 - -Notifying the patient by telephone with the ability to use a friendly familiar voice ("Dad, it's time...") or a computer generated call;
 - -Putting a notification on the patient's television(s);
 - -using a LED screen to notify the patient.
- 7. An LED screen by the medicines storage space will display the names of the proper one(s) and the doses to be taken.
- 8. The patient passes his medication by the Bar Code reader of the MEDS-ALERT USA INC. unit and is notified that the medication is correct. The system notifies the central system that the correct action has or has not been taken. The MEDS-ALERT USA INC. system may poll the patient to ask if he has taken the medicine. The patient may respond to an inquiry by pressing a button on the unit or responding to an automated telephone inquiry.

FUTURE: The MEDS-ALERT USA INC. unit dispenses the medications from cassettes and senses when they are removed.

FUTURE: A video camera may observe the patient taking the medicine.

MEDS-ALERT USA INC.

1451 PARKVIEW TERRACE S. ALGONQUIN, IL 60102

847 – 658 – 6784

DESCRIPTION OF SERVICE – (continued)

FOLLOW-UP

- 9. If a problem is detected or suspected with the patient's regimen, The MEDS-ALERT USA INC. system will respond in a variety of ways:
 - -Flash a warning to the patient on the unit's LCD screen and/or
 - -Flash a warning to the patient of the television and/or
 - -Sound an alarm and/or
 - -Warn the patient through a speaker and/or
 - -Call the patient and/or
 - -Call the persons designated care-giver (neighbor, relative, doctor or other).
- 10. After a problem is detected or suspected with a patient the MEDS-ALERT USA INC. central service system will initiate a follow-up program that includes checking on the immediate problem as well as for the suitability of the patient to continue with the program as determined by the entity in charge of the patient's care.
- 11. When a prescription or medical disposable appears to need refilling or restocking, the MEDS-ALERT USA INC. system will notify:
 - -The patient;
 - -The patient's prescribing and general physicians;
 - -The patient's care-giver;
 - -The healthcare provider.

FUTURE

FUTURE: The MEDS-ALERT USA INC. system can be expanded to:

- -Account for medical expendables (pampers, needles, sanitary napkins, etc.)
- -Used to monitor a patient's well being:
 - -Motion detector(s) (is the patient moving, breathing?);
 - -Panic button(s) ("Help! I've fallen and I can't...");
 - -Automated pulse and blood pressure measurement;
 - -Automated blood sugar level (diabetes, hypoglycemia) measurement;
 - -Location of patient (beginning Alzheimer's);
 - -Automated blood oxygen level;
 - -Oxygen tank monitoring systems;
- -Record and report on in-home care-givers activities;
- -Dispense non-prescription health aids (vitamins, ant-acids, candy for diabetics etc.).
- -Monitor nutrition (is the patient eating and at proper times(diabetes)).

THE MEDS-ALERT USA INC. UNITS

The MEDS-ALERT USA INC. system is built with a variety of off the shelf items.

The heart of the remote unit is a Bar Code reader or any other system that detects and records objects used in in-home patient care.

The remote unit will have a backup power source (battery) to protect against power outages.

The remote unit will have an EEPROM memory so that it can continue to function if the communications methods are interrupted or the central service system is down.

The remote unit will use telephone lines, satellite or cable for communication (the Internet is not considered to be reliable and secure enough).

The remote unit will be polled from the central service system periodically (at least once daily) to verify it is functioning. The central service system will notified by the remote unit of any problems with the patient or the remote unit itself.

Various modems will be used to connect the remote unit to the central service system with telephones, video (the patient's televisions, computers), LCD screen, and/or video camera.

PROFIT CENTERS OPERATING ENTITIES

The MEDS-ALERT USA INC. system operation has these functions:

- -Software design;
 - -Central system and remote units;
- -Hardware design;
 - -Central system and remote units;
- -Hardware Supplier;
 - -Central system and remote units;
- -Software installation and maintenance;
 - -Central system and remote units;
- -Communications supplier(s) (land line, cellular, satellite, cable);
- -Remote unit delivery, installation, and customer training;
- -Remote unit maintenance and repair:
- -MEDS-ALERT USA INC. service sales and marketing;
- -MEDS-ALERT USA INC. central service and remote unit monitoring.

All of these functions are profit centers. Obviously the major one is the MEDS-ALERT USA INC. central service system. The monitoring system polls the remote units, monitors the patient's medication regimen, reacts to problems and notifies the healthcare provider of the need to refill prescriptions.

DEVELOPMENT

MEDS-ALERT USA INC. can develop an operating prototype in 6 to 8 months. This prototype can go directly into production since it will be assembled totally with off-the-shelf components. An advanced system prototype, using cassette dispensers and video cameras can be developed in an additional 8 months.

In essence, the system is an interactive cable television set-top box with added features.

The unit will be designed to communicate via:

- -Cellular telephone systems and/or
- -Land telephone lines and/or
- -Cable connection and/or
- -Satellite communications.

The system will not use the internet because of security and hacking concerns.

The unit will have its own memory backup and power backup in case of central server system failure or power outages. Changes to the programming of the patient's medication protocol will be done over secure communication lines. The unit will be built with anti-tamper protection. The medication cassettes, once inserted, will be protected against tampering, breaking and opening or dispensing outside of the unit's protocol. The exception will be a locally and/or remotely triggered emergency drug dispenser (for seizure onset symptoms, heart conditions, etc.) that will be enabled for special patients.

The steps for the development of the MEDS-ALERT USA INC. system are:

- -For the central service system system:
 - -Software design;
 - -Hardware design;
 - -Communications protocol;
 - -Hardware assembly (off-the-shelf);
 - -Software installation.
- -For the units:
 - -Software design;
 - -Hardware design;
 - -Communications protocol;
 - -Hardware assembly (parts are off-the-shelf);
 - -Software installation.

DEVELOPMENT – (continued)

MEDS-ALERT USA INC. has an informal agreement with the University of Tennessee College of Pharmacy and the University's Engineering Department to construct the alpha and beta units of the MEDS-ALERT USA INC. system. The School of will then test the beta units. The estimated cost is \$2M plus and endowment to the School of MEDS-ALERT USA INC. stock.

Dr. Dick R. Gourley, Pharm D
Dean of the Health Service Center
University of Tennessee
College of Pharmacy

PATENTS GRANTED

efficiency for the control of the co

MEDS-ALERT USA INC. owns two patents. They were purchased from Charles T. O'Brien. They are:

PATENT 5,963,136
Oct. 5, 1999
"INTERACTIVE PRESCRIPTION
COMPLIANCE AND LIFE SAFETY SYSTEM"

-PATENT 6,150,942
Nov. 21, 2000
"INTERACTIVE PRESCRIPTION
COMPLIANCE AND LIFE SAFETY SYSTEM"

The patents have been granted for:

- -United States:
- -Canada:
- -Western Europe;
- -Taiwan:
- -Hong Kong.

The patents have already been tested in court and have prevailed in "Early Warning v. O'Brien" 3/23/2000, United States District Court, Northern District of Illinois.

These patents were developed by and purchased from Charles T. O'Brien, the Company's largest shareholder.

The essence of these patents is:

- -Use of an in-home Bar Code reader (or other electronic reader) to assure:
 - -Control and Monitoring of the dispensing of medicines in the home;
 - -Adherence to the proper regimen (dosing and timing) of their use.
- -Interactive verification of a proper medication regimen by the patient.

PATENT APPLICATION

"RESCRIBE" "PRESCRIPTION FULLFILLMENT VERIFICATION SYSTEM"

There is currently very minimal communication from the pharmacist back to the physician. "RESCRIBE" is a service to verify to the physician and healthcare provider that the patient's prescription has been properly filled. This double-check will greatly reduce the few, but very devastating, mistakes made by miscommunication.

This patent covers a return communication from the pharmacy to the prescribing physician, general physician and healthcare provider:

- -Verifying that the prescription has been filled;
 - -Generic or Proprietary;
 - -Substitution:
 - -Dosage;
 - -Quantity;
 - -Regimen for consumption;
 - -Time;
 - -With or without food (no grapefruit juice..) or water;
 - -Restrictions (no alcohol);
 - -Refill information:
 - -Refills left;
 - -Refills used:
 - -Interval since last refill;
 - -Other Patient prescriptions;
 - -Conflict between medicines and/or other things (herbs, vitamins, minerals);
 - -Patient information:
 - -Doctor information:
 - -Pharmacy information

These responses from the pharmacy will be generated automatically as the prescription is filled.

The MEDS-ALERT USA INC. "RESCRIBE" system will also notify:

- -The patient;
- -The patient's prescribing and general physicians
- -The patient's care-giver
- -The healthcare provider

when a prescription of medical disposable appears to need refilling or restocking.

MEDS-ALERT USA INC.

COPYRIGHTS

MEDS-ALERT USA INC. is copyrighting the description of its service and computer programs.

TRADEMARKS

MEDS-ALERT USA INC. is applying for a trademark on its name.

THE COMPANY

MEDS-ALERT USA INC. is an Illinois C corporation. It has several shareholders. The majority shareholders are Charles T. O'Brien and Roberta L. O'Brien (husband and wife).

Directors

Charles T. O'Brien, Chairman Roberta L. O'Brien, Secretary.

Officers

Charles T. O'Brien, President Roberta L. O'Brien, Vice President.

Advisor to the Company

Dr. Dick R. Gourley, Pharm D
Dean of the Health Service Center
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White Paper

Meds-Alert USA, INC.

Care of the elderly and chronically ill is one of the most vexing problems facing the United States, or for that matter, the entire developed world, and this group will continue to grow through the year 2040. Automated care must be implemented or the economies of the United States and the rest of the developed world will suffer profound and irreparable damage.

Meds-Alert holds the <u>only</u> patent utilizing Bar Codes for identifying prescriptions, supplies and caregiver identity.

A national barcode standard for healthcare is now possible.

The college of Pharmacy of the University of Tennessee has joined with Meds-Alert to aid in the development of this system.

Terry O'Brien 1451 Parkview Terrace South Algonquin, Illinois 60102 847-658-6784

Meds Alert Raises Prescription Compliance and Reduces Medicare Fraud

Prescription non-compliance in the United States annually costs the economy \$70 billion, according to Dr. Richard Gourley, Dean of the College of Pharmacy, University of Tennessee. Medicare fraud costs the Centers for Medicare and Medicaid Services \$13 billion per year, which does not include individual state costs. Medicaid housing expenses for those institutionalized in Illinois, alone, in 1997 were \$3 billion. The national average for a one-year nursing home stay is currently \$48,000 per person. Twenty five percent (25%) of nursing home residents are there, primarily, because of their inability to correctly take their prescribed medications, according to a 1999 Federal Drug Administration study. A 1999 study conducted by a major drug retailer, states that the Meds-Alert system would keep a person out of a nursing home an average of two and one half (2-1/2) years beyond the onset of dementia. The state of Illinois would save up to \$600 million per year on Medicaid housing costs alone. Shortages of qualified pharmacists and caregivers will reach epidemic proportions by the year 2005. The Veterans Administration projects that it will run out of caregivers by 2005. There are currently 10,000 vacant pharmacy positions with no one to fill the positions, according to Drug Store News, a trade publication.

These are staggering statistics and the numbers are rising each year. Health care costs in the United States are currently one trillion (\$1,000,000,000,000) dollars annually and are expected to double by the year 2005, with the arrival of the Baby-Boomers, according to surveys conducted by the "Chicago Tribune" and the "Chain Drug Review". This exponential growth is expected to continue through the year 2040.

With the Meds-Alert system, a non-medically trained person can oversee the medical care of an individual

The College of Pharmacy of the University of Tennessee has entered into an agreement with Meds-Alert to aid in the full development of the Meds-Alert system.

Battelle Memorial Institute has termed Meds-Alert's patented technology as "Disruptive Technology with an economic impact in the billions of dollars" and has committed it's resources to completely developing the system's full potential.

Meds-Alert's system is not limited to use by the elderly. Any recovering patient could easily be monitored and would reduce the need for close supervision by a caregiver. Organtransplant, cancer and AIDS patients have very complex drug regimens, which must be followed precisely. Prescription non-compliance, in these cases, would result in organ rejection or death. Short-term use is feasible because the system does not require permanent wiring, thus installation and removal is easily accomplished.

The Veteran's Administration could well be the first customer and has verbally committed to conducting Alpha and Beta pilot testing programs of the Meds-Alert system at Hines, Illinois.

The "baby-boomers" have a much greater acceptance of computers than do their parents. Therefore, we can expect overwhelming acceptance of the Meds-Alert system when the need for it will be greatest. Baby boomers have potential to overwhelm the current health care system.

Meds-Alert's unique system is protected by **two patents** recently issued. The original patent was awarded within **six months** of the application date, under the "application to make special" provision. The Meds-Alert patent was deemed able to provide significant help for **cancer** and **AIDS** patients, and is anticipated to have a profound impact on society.

Meds-Alert has also been granted, and has in-process, international patent protection in England, France, Germany, Spain, Italy and Canada as well as Hong Kong and Taiwan.

Several United States Senators and Congressmen, as well as Governor George Ryan, of Illinois, have expressed interest in implementing the Meds-Alert technology. Governor Ryan wrote recently: "Having been a pharmacist, I am interested in this project because it has the potential to provide significant cost savings to the taxpayers. The Meds-Alert System has the potential to help control fraud so that health care dollars can be directed to the underserved and uninsured."

The open-architecture design of the Meds-Alert system allows for the easy expansion of the basic system without any redesign. A transition from Bar Code to radio-frequency identification (RFID) tags, for example, could be easily accomplished.

The heart of the system is an embedded controller. Meds-Alert's staff has over 100 years experience in all phases of embedded controller design. Richard Alderman, a "Senior Fellow of Honeywell", designed the first digital keyboard. Richard Barthel, Senior automotive Engineer of Delphi Mechantronic Systems, designed the first digital appliance controller. John Bowman has thirty-five years of software/hardware project management. Burt Schultz designed and built one of the first prototype computer-controlled kidney dialysis systems. Meds-Alert owns two patents and its staff are signatories to seventeen other patents.

Only the Meds-Alert system embodies a unique technology mix and a migration path utilizing RFID tags and a medication dispenser, which is filled and bar-coded by an automated pharmacy implementing unit dose packaging, thus eliminating any possibility of "mixed-up" meds. Additionally, the Meds-Alert system does not require a personal computer.

The entire Health care industry is migrating to *Unit Dose packaging*, as indicated in white papers published by: the United States Pharmacopoeia (USP) and the Uniform Code Council (UCC). (Meds-Alert participated in this study.)

There are other systems, none of which, however, possess the technology of the Meds-Alert system. One system, for instance, uses an RFID tag to inform the patient what medication is in the pill vial. It does not, however, cue the patient when it is time to take the medication, nor does it record the event – the Meds-Alert system accomplishes both functions. Another system utilizes a drawer system to be installed in the home. Yet another system uses a medication cup and a similar signaling method. These systems are activated via a signal from a central station, but suffer from two major flaws. First, a non-pharmacist fills the drawers in

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the patient's home, so prescription traceability is lost and the potential for **medication errors** can soar simply by placing the meds in the wrong drawer. Second, a personal computer, is required to operate the system, and is not included.

Other systems offer the panic buttons or pendants, "Help, I've fallen down". Still others offer medical monitors, such as blood pressure readings, E.K.G. reports or other physiological functions. One system even uses a Global Positioning System (GPS) receiver to track the physical position of a patient. Meds-Alert's patents include panic buttons, medical monitors, tracking devices and other features.

The Meds-Alert system signals (cues) the patient when it is time to take medication, verifies that the event has occurred, then records the event. This creates a complete prescription compliance log for each patient, which is essential for physicians, caregivers and other service providers. Meds-Alert can monitor medical conditions, such as blood pressure, E.K.G., as well as the state or condition of various life-support systems such as oxygen tanks or generators, infusion pumps and more. The system also includes panic buttons and could incorporate a GPS tracking system to alert caregivers when the patient wanders.

The Meds-Alert system also uses audio/visual alarm cueing, and, in addition, scrolls a message to take medications on the screen of the home unit or on the patient's own television set. These patented features, additionally, allow Meds-Alert to provide the patient with valuable information regarding specific health instructions, and ADL's such as "Mr. Johnson, have you eaten your breakfast yet? This medication must be taken with food!" Meds-Alert also monitors Life-Safety alarms such as smoke, fire, electricity and temperature.

The patent office has granted Meds-Alert the communication means of the Public Switched Telephone Network (PSTN), wireless (cell phone) and satellite (GPS/cable).

Meds-Alert raises prescription compliance

Meds-Alert is the only system capable of logging the caregiver's visit by recording not only the date, arrival and departure times, but also the caregiver's identity and type of care.

Meds-Alert can, immediately, provide third-party billing upon completion of service.

Meds-Alert's unique, patented system is the only one capable of logging/tracking medical supplies such as walkers, wheelchairs and canes or disposables such as diapers, pads and bandages in the patient's home or institutional setting. These areas are major sources of fraud. No other system provides life-safety monitoring such as smoke, fire, water, temperature or burglar alarms. No other system provides the capability for a family member the ability to check on their loved one's condition from a remote location via the Meds-Alert "Family Area NetworkTM".

Meds-Alert:

- · Raises a patient's prescription compliance
- Monitors medical devices
- Tracks the activities of caregivers
- Records the delivery and use of medical supplies
- Provides third party billing
- · Monitors life-safety devices
- Allows worldwide access by a family member to a patient's condition

Because Meds-Alert monitors and records all aspects of a patient's care, a patient profile and electronic inventory can be created and maintained. Meds-Alert provides a safe, secure environment for patients to be cared for in their own homes or their institution. Patients and caregivers, along with their meds and other supplies, are linked to a single, secure database.

Meds-Alert's pricing structure includes a "lease option" for the home unit. A monthly (subscription) monitoring fee will be charged for the basic Prescription Compliance service. Other services such as life-safety monitoring will also be charged monthly and added to the cost of basic service. This price structure is similar to a monthly cable television or telephone service invoice.

The State and Federal governments may pay a portion or all of the costs of the Meds-Alert system. The reason is quite simple: Meds-Alert saves taxpayer's money, reduces fraud and could facilitate Medicare/Medicaid billing.

Multiple revenue sources are created by Meds-Alert:

- Net profits from the sale or lease of the home unit.
- · Monthly monitory fees.
- Agent/Distributor licenses.
- Installation fees.
- Distribution of Medicare/life style supplies.
- Third-party billing for private pay or Medicare/Medicaid

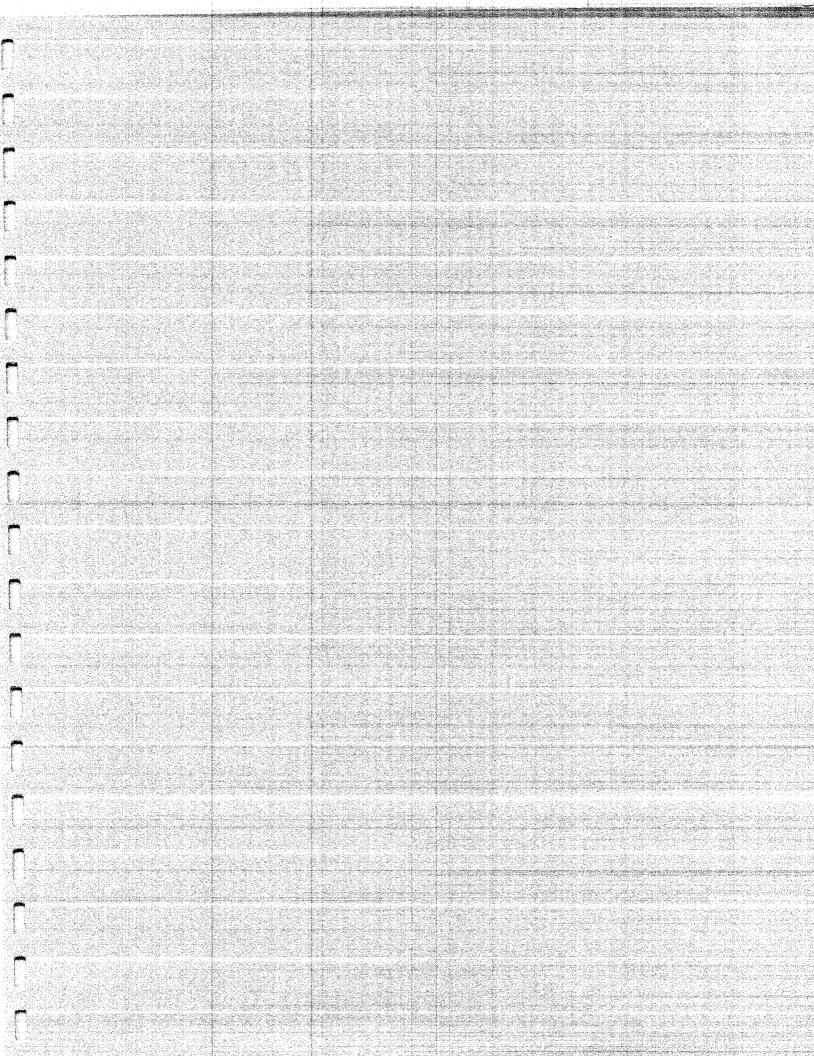
"The aging populations of developed countries are economic time-bombs that can be defused only by overhauling pension programs and expanding employment opportunities" – "The challenges of global aging are fundamental, unprecedented and potentially destabilizing to global prosperity"; Summary statements from report adopted by *The Commission on Global Aging*. Tokyo conference organized by the Washington-based *Center for Strategic and International Studies*, co-chaired by former Vice President Walter Mondale and former Japanese Prime Minister Ryutaro Hashimoto. From the *Chicago Tribune*, Thursday, August 30, 2001.

"Meds-Alert is poised with a solution"

The Re-Scribe System

Re-Scribe ™ (patent pending) is the Meds-Alert system for notifying the patient's doctor with confirmation that a particular prescription has been filled on what date. This provides the doctor with a confidence level that the patient is complying with the prescription instructions.

Full details of the Re-Scribe system's operation are available upon execution of a non-disclosure agreement.



Take Your Medicine

HMOs are using a new service to manage their sickest patients

BY DANIEL EISENBERG

ince hmos have done such a sorry job of managing care for healthy folks, how in the world are they ever going to do it for the sickest Americans? That's the vexing question facing health insurers and employers as they try to deal with the growing ranks of the chronically ill—a number that is expected to double, to close to 180 million, in the next few decades.

Though they make up 45% of the population, patients who suffer from heart disease,

diabetes, asthma, AIDS and other long-term maladies account for nearly 80% of all health-care costs—often winding up in the emergency room or a hospital bed when they fail to follow their complicated medication regimen. If you are one of them, don't be surprised when your employer or health insurer introduces you to a specialist in the burgeoning field of disease management. The basic idea is relatively simple: led by a company called American Healthways, these newfangled Florence Nightingales, among them Lifemasters and Matria, help monitor the most at-risk patients.

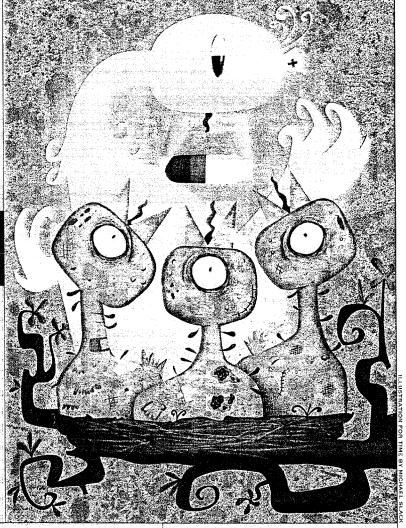
Think of them as Big Mother. Though they don't actually practice medicine, companies like American Healthways use the Internet and other high-tech equipment to keep track of your vital statistics and your treatment, reminding you to take your medicine or schedule a followup exam with the doctor. On rare occasions, and at the last minute, they might even drive you to, say, a dialysis clinic if no other options are available.

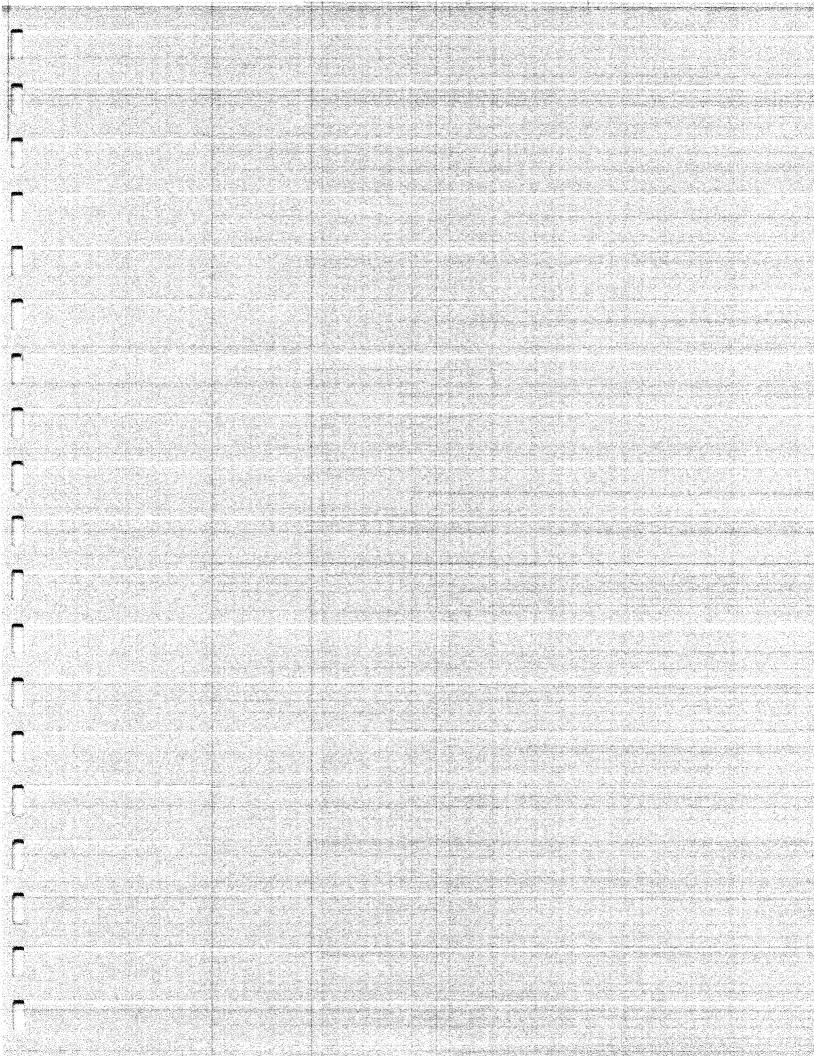
In the past few months, big insurers such as Aetna, Cigna and various Blue Cross/Blue Shields have signed contracts, paying as much as \$20 a month per member to have chronics looked after. Medicare and many state Medicaid programs are already experimenting with the idea. Even pharmacies and pharmaceutical firms are rolling out disease-management programs to make sure people keep popping those lucrative pills. "Less than 25% of the time, everyone in the health-care system is doing what they're supposed to do," says Richard Rakowski, president of American Healthways, whose stock has soared sevenfold, to nearly \$35, in the past year. "We are an invisible hand to fill in those gaps."

Now if you don't want Big Mother lending a helping hand, you can just say no (an option not always available when Mom was in charge). But so far, most patients have jumped at the chance to get the special treatment.

Obviously, the HMOs would like to save a buck or two in the process. Although many observers are skeptical that all this hand-holding can actually cut costs, American Healthways, which is trying to market what it calls "care enhancement" to all patients, insists that insurers will save \$3 for every \$1 they pony up.

"The old setting of care, the traditional office visit, was created to take care of acute medical problems a century ago," says Dr. Victor Villagra, president of the Disease Management Association of America and a national medical executive at Cigna, which already has more than 600,000 members enrolled in chroniccare programs and has seen a 14% cost savings for diabetic patients who are participants. "That is no longer sufficient," he says. What is, apparently, is having someone there to tell you to take your medicine, or else.







OFFICE OF THE GOVERNOR 207 STATE CAPITOL, SPRINCFIELD, ILLINOIS 62706

GEORGE H. RYAN GOVERNOR

August 16, 2000

Ms. Nancy-Ann Min DeParle
Administrator
Health Care Financing Administration
200 Independence Avenue SW
Washington, DC 20201

Dear Ms. DeParle:

I am writing in support of the grant application from Meds-Alert USA, Inc. to the Health Care Financing Administration (HCFA). Members of my staff reviewed the system and believe it has applicability in Illinois. Having been a pharmacist, I am interested in this project because it has the potential to provide significant cost savings to taxpayers.

The Illinois Department on Aging has expressed interest in serving as a pilot for the first Beta Site for Meds-Alert's patented Interactive Prescription Compliance and Life-Safety System. I support their enthusiasm and interest in this program.

Illinois is recognized nationally as a state that has taken Medicaid and Medicare fraud seriously. The Meds-Alert System has the potential to help control fraud so that health care dollars can be directed to the underserved and uninsured. For these reasons I am supportive of their application.

Georg H Hyan

GEORGE H. RYAN

Governor